

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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IN RE: Bair Hugger Forced Air Warming  
Products Liability Litigation

MDL No. 2666 (JNE/FLN)

This Document Relates to:

**PLAINTIFFS' OPPOSITION TO  
DEFENDANTS' OBJECTION TO  
ORDER REGARDING UNSEALING  
OF DOC. 937**

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Pursuant to L.R. D. Minn. 5.6 and 72.2(a), Plaintiffs oppose Defendants' Objection [Dkt. 1258] to Magistrate Judge Noel's March 23, 2018 Order [Dkt. 1247] pertaining to the joint motions regarding continued sealing.<sup>1</sup> Plaintiffs respectfully request that the Court deny Defendants' attempted appeal of Judge Noel's Order.

**INTRODUCTION**

The public has a right to access records which the Court utilized as the basis of their opinions, especially when those records are used in open court. Not only does it go to the public interest, but in this case, it goes to public health and safety. Defendants have failed to warn of the risks of the Bair Hugger device. Defendants do not need a study or medical literature about their device to have a duty to warn. If such were the standard, many products would not have warnings. Rather, corporations can – and indeed must - utilize basic engineering principles to determine the dangers of their devices. Here, Defendants have long been aware that this device had the potential to cause

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<sup>1</sup> See Dkt. 1002, 1003, 1005, 1006, 1007, 1009, and 1010.

airborne contamination. This is evident in the sealed documents and the warnings on Defendants' previous devices. It is foreseeable that a prudent person—here, an orthopedic surgeon—would utilize the information in these documents to take effective precautions. *Liberty Mut. Ins. Co. v. CFC, Inc.*, CIV 08-859 JNE/SRN, 2009 WL 3517867, at \*5 (D. Minn. Oct. 23, 2009). Limiting the public access to these documents may prevent scientific research and effective precautions by the medical community. Unsealing these documents in no way provides a competitive advantage to any of the Defendants' competitors—for instance, Stryker's Mistral forced air warming device already includes a warning about airborne contamination.

In entering its Order of March 23, 2018,<sup>2</sup> the Court determined that several documents which have been discussed in detail during public hearings before the Court with no objection from Defendants at the time of said hearing; and/or which did not meet the requirements of being deemed confidential under the Protective Order entered in the case<sup>3</sup> should be unsealed. Defendants filed a Motion for Further Consideration of Sealing with respect to a single unsealed document: Doc. 937.<sup>4</sup>

The document in question could potentially be useful to medical professionals, such as orthopedic surgeons, with respect to the health and safety of their patients. This document may lead to further medical research in the patient warming field to protect patients. The fact that this document does not put Defendants in a good light or may cause minor economic harm is irrelevant. The issue is whether Defendants have any legal

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<sup>2</sup> Dkt. 1182.

<sup>3</sup> Dkt. 39, Pretrial Order No. 7: Protective Order.

<sup>4</sup> Dkt. 1223.

basis to keep these documents from the public, especially when the documents were presented in a public forum and relied upon by the Court to form judicial opinions.

It is important to note that the document at issue does not contain the type of technical or proprietary information which the Protective Order was primarily designed to protect. In fact, with respect to the Bair Paws document<sup>5</sup> regarding Defendants' knowledge that interoperative warming is contraindicated for orthopedic surgery, Defendants' fail to inform the Court that the document is not an internal document but a document that was emailed to Cindy Quint, an employee of Underwood Memorial Hospital.<sup>6</sup>

### **ARGUMENT**

#### **I. The Court Properly Concluded Public Interest Supports Unsealing of Document in Question**

Pursuant to Local Rule 72.2(a), Judge Noel's Order is entitled to significant deference, and may only be set aside if it is "clearly erroneous or contrary to law." L.R. 72.2(a).

There is a strong public interest afforded by both the First Amendment and common law in allowing public access to court proceedings and records. *See, e.g., Webster Groves Sch. Dist. V. Pulitzer Publ'g Co.*, 898 F.2d 1371, 1376 (8th Cir. 1990); *Ass. Press v. District Court*, 705 F.2d 1143, 1145 (9th Cir. 1983); *Healey v. I-Flow, LLC*, 282 F.R.D. 211, 214 (D.Minn. 2012); *NBC Subsidiary (KNBC-TV), Inc. v. Superior*

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<sup>5</sup> Dkt. 937.

<sup>6</sup> Ex. A, Email Correspondence Between Al Van Duren and Cindy Quint with Underwood Memorial Hospital Regarding Test Proposal, Dated Nov. 1, 2007.

*Court*, 980 P.2d 337, 358 (Cal. 1999); *Mokhiber v. Davis*, 537 A.2d 1100, 1107 n. 4 (D.C. 1988). The Eighth Circuit acknowledges that there is a presumption that a right to public records exists absent “compelling reasons [to] justify non-disclosure.” *In re Neal*, 461 F.3d 1048, 1053 (8th Cir. 2006). The Protective Order entered in this case acknowledges as much, stating that the “[o]rder will be construed in favor of public disclosure and open proceedings wherever possible” to support the “presumption in favor of open and public judicial proceedings in federal courts.”<sup>7</sup>

The Eighth Circuit has established that the public has a right of access to records and documents that form the basis of judicial opinions in civil proceedings. *IDT Corp. v. eBay*, 709 F.3d 1220, 1222 (8th Cir. 2013); *see also Aviva Sports, Inc. v. Fingerhut Direct Mktg, Inc.*, 960 F. Supp. 2d 1011, 1013 (D.Minn. 2013). This requires a weighing of the balance between the public’s interest in access to court records against the “salutary interests served by maintaining confidentiality of the information sought to be sealed.” *IDT Corp.*, 709 F.3d at 1222. The weight afforded to the presumption of access “must be governed by the role of the material at issue in the exercise of Article III judicial power and resultant value of such information to those monitoring the federal courts.” *Id.* at 1224; *see also Skky, LLC v. Facebook, Inc.*, 191 F. Supp. 3d 977, 980–81 (D.Minn. 2016) (presumptive right of access was “particularly strong” where document sought to be sealed pertained to a motion to transfer venue); *Healey v. I-Flow, LLC*, 282 F.R.D. 211, 214 (D.Minn. 2012) (noting a “heightened burden [exists] to overcome the presumptive right of the public access to the briefs and supporting documents at issue

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<sup>7</sup> Dkt. 39, Pretrial Order No. 7: Protective Order, p. 2.

because [they] were filed with the [c]ourt in connection with a merits-based motion”).<sup>8</sup> Thus, the right to public access is further heightened when the ruling from the court for which the document is relied upon is dispositive or merits-based.

The party attempting to seek restrictions on public right of access to court proceedings bears the burden of showing good cause to support access restrictions. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 785-86 (3rd Cir. 1994) (noting that good cause requires showing that disclosure will cause a clearly defined and serious injury, which must be demonstrated with specificity) (quotations omitted); *Miscellaneous Docket Matter # 1 v. Miscellaneous Docket Matter # 2*, 197 F.3d 922, 926 (8th Cir. 1999) (adopting *Pansy*). One of the factors relevant in considering whether to restrict or deny public access is whether confidentiality is being sought over information important to public health and safety. *See Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3rd Cir. 1995); *see also In re National Hockey League Players’ Concussion Injury Litigation*, 2016 WL 1328919, \*5 (D.Minn. March 5, 2016) (analyzing “public health and safety” factor in finding that Magistrate Judge did not err by ordering the de-designation of portions of documents “that involved issues germane to the lawsuit and important to the health and safety of the public.”); *Healey*, 282 F.R.D. at 214 (“Secreting evidence that

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<sup>8</sup> The court in *Healey* also expressed concern that maintaining sealing of documents used by the court to reach a determination “could require the court to circumscribe its opinion explaining the decision so that secrets are not revealed or, worse still, result in a blacked-out redacted opinion that looks like it came from a top secret spy agency file.” *Id.* at 215.

underlies a judge’s decision conflicts with . . . important goals” to protect public health and safety concerning use of the medical device in question).<sup>9</sup>

Defendants have failed to demonstrate with specificity any clearly defined and serious injury that satisfies the “good cause” requirements for sealing the Court proceedings and files. They instead allude to hypothetical competitive harm that could result if this single document is unsealed and made accessible to the public,<sup>10</sup> or the potential impact on the *Gareis* trial due to adverse publicity. [Dkt. 1258 at 1] Given the conclusion of the *Gareis* trial, there can be no legitimate concern about the risk of adverse publicity on the outcome of the trial. Defendants do not go into detail aside from merely giving a description of the document in question, asserting the Plaintiffs have taken the document out of context, and next claiming that Augustine will use the document. As Defendants have made absolutely no showing as to how allowing public access to this document will cause serious injury. The document has been read from and displayed, multiple times, in open Court proceedings, with members of the press in the gallery.

As the weight in favor of public access of these documents is significantly greater than it was when this Court considered the document previously, Plaintiffs respectfully oppose Defendants’ Objection to the Order.

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<sup>9</sup> There is a clear parallel in terms of use by the public at large between the Pain Buster pain pumps involved in *Healey* and the Bair Hugger device at issue in this litigation.

<sup>10</sup> See, e.g., Dkt. 1258, pg. 2 (document “*likely* to be subjected to a significant degree of competitive harm if the document is made public”) (emphasis added); see also Section II, *infra*.

## II. Documents Should Not Remain Sealed Based on Defendants' Assertions Alone

Bare assertions that public access to “confidential and sensitive business [information] . . . could give competitors a distinct competitive advantage” are insufficient to justify a document remaining sealed. *Skky, LLC*, 191 F. Supp. 3d at 981 (motion to seal denied because defendants “ha[d] not presented *any* factual basis for sealing th[e] information from public access”) (emphasis theirs)<sup>11</sup>; *see also Miscellaneous Docket Matter # 1 v. Miscellaneous Docket Matter # 2*, 197 F.3d 922, 926 (8th Cir. 1999) (citing *General Dynamics Corp. v. Seib Mfg. Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973)) (good cause is required to be based on specific demonstrations of fact); *Healey*, 282 F.R.D. at 215 (“[C]ontinued sealing must be based on current evidence to show how public dissemination of the pertinent materials now would cause the competitive harm claimed.”) (quoting *In re Cendant Corp.*, 260 F.3d 183, 196 (3rd Cir. 2001)); *Lubrication Technologies, Inc. v. Lee’s Oil Service, LLC*, 2012 WL 1633259, \*13 (D.Minn. Apr. 10, 2012) (“Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning do not support a good cause showing” for confidentiality) (quoting *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 484 (3rd Cir. 1995)); *Plan Pros, Inc. v. Zych*, 2009 WL 562348, \*1 (D. Neb. March 5, 2009) (same). “[C]ourts traditionally require that the party wishing to have confidential information in the court record kept under seal show that disclosure of the information will result in

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<sup>11</sup> The court further stated that “the information [defendants] seek to file under seal is not the type of sensitive information that might typically be subject to an order to seal, such as financial data [and] proprietary or trade secret information.” *Id.*

some sort of *serious* competitive or financial harm.” *Healey*, 282 F.R.D. at 215 (quoting *Tinman v. Blue Cross & Blue Shield of Michigan*, 176 F. Supp.2d 743, 745 (E.D. Mich. 2001)) (emphasis added).

Defendants assert that this document should remain sealed due to hypothetical competitive harm which may befall them in the event it were to be made public, or the potential impact on the *Gareis* trial due to adverse publicity. [Dkt. 1258 at pg. 1] Given the conclusion of the *Gareis* trial, there can be no legitimate concern about the risk of adverse publicity on the outcome of the trial. Defendants do not go into detail aside from merely giving a description of the document in question, asserting the Plaintiffs have taken the document out of context, and next claiming that Augustine will use the document. These assertions are insufficient to overcome the presumption in favor of public access to documents used in public proceedings in this Court. In the absence of any evidence or specific demonstrations of fact regarding potential **serious** harm, these claims amount to no more than bare assertions of hypothetical harm and should be insufficient to allow the continued sealing of these documents.

### **III. Defendants Waived any Assertion of Confidentiality on All Documents Discussed During the Public Hearing**

The information contained in the document at issue was discussed at length during the hearing regarding the respective motions for which each was filed to support. Documents used in open court which contain trade secrets or other proprietary information necessarily have their confidential status “destroyed . . . [by] use[] in open court during [a] motion hearing.” *In re Guidant Corp. Implantable Defibrillators Product*



*Liability Litigation*, 245 F.R.D. 632, 637 (D. Minn. 2007). Any document—or passages of a document—referred to or discussed during the hearing should therefore be unsealed.

Defendants have made no attempts to seal the proceedings where these documents were discussed in detail, whether by requesting confidential designations in the transcript or other mechanism. Defendants also made no attempts to work with the Court prior to the hearing to restrict access to the hearing over any apparent concern over the divulgement of allegedly confidential information, even though Defendants had reason to expect that members of the press and general public would be present for the duration of the three-day hearing in October 2017. Defendants have essentially acquiesced to the disclosure of the information discussed during the hearing, so for the documents referenced and displayed during that hearing to remain under seal is inconsistent with Defendants' prior handling of the supposedly confidential and competitively harmful information.

**IV. Response to Defendants' Motion: Bair Paws Document is Not Just an Internal Document and Therefore Not Confidential**

Defendants object to the Order unsealing one of the Bair Paws documents<sup>12</sup> but fail to inform the Court that the document should not have been designated confidential in the first place.<sup>13</sup> The Bair Paws document was emailed to a non-employee of Defendants when Mr. Van Duran was shopping around the test protocol for providers to

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<sup>12</sup> Dkt. 1224, Memorandum in Support of Defendants' Motion for Further Consideration of Order on Joint Motion Regarding Continued Sealing.

<sup>13</sup> Dkt. 937.

perform a new pre-warming study.<sup>14</sup> It is clear that at least by 2007 that Al Van Duran, Director of Clinical Affairs, was aware of the risks of intraoperative warming and that it was contraindicated for orthopedic surgery.<sup>15</sup> He was also aware that the Bair Hugger device did not have any warning indicating that it may potentially cause airborne contamination.

Defendants waived any confidentiality when Defendants provided the Bair Paws document to a third party. There is no indication in the email or document that protocol is confidential or privileged. As a result, there is no basis for confidentiality and therefore continued sealing. Plaintiffs respectfully request Defendants' Objection to Judge Noel's Order be denied.

### **CONCLUSION**

Defendants' have advertised and promoted the alleged safety of the Bair Hugger on their websites and publishing Court orders, FDA letters, deposition transcripts, etc.<sup>16</sup> Defendants are utilizing this Court to promote the safety of the Bair Hugger while at the same time requesting the Court to hide from the public the documents presented at the dispositive hearings.

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<sup>14</sup> Ex. A, Email Correspondence Between Al Van Duren and Cindy Quint with Underwood Memorial Hospital Regarding Test Proposal, Dated Nov. 1, 2007.

<sup>15</sup> *Id.*

<sup>16</sup> <http://www.bairhuggerfacts.com/blog/>; <http://www.truthaboutbairhugger.com/blog-2017>.

For the reasons stated above, Plaintiffs respectfully request that Defendants' Objection to Magistrate Judge Noel's March 23, 2018 [Dkt. 1182] Order regarding Doc. 937 be denied.

Respectfully submitted,

Dated: June 6, 2018.

CIRESI CONLIN L.L.P.

/s/Michael V. Ciresi  
Michael V. Ciresi (MN #0016949)  
Jan M. Conlin (MN #0192697)  
Michael Sacchet (MN # 395817)  
Ciresi Conlin LLP  
225 S. 6th St., Suite 4600  
Minneapolis, MN 55402  
Phone: 612.361.8202  
Email: MVC@CiresiConlin.com  
JMC@CiresiConlin.com  
MAS@ciresiconlin.com

MESHBESHER & SPENCE LTD.

/s/ Genevieve M. Zimmerman  
Genevieve M. Zimmerman (MN #330292)  
1616 Park Avenue South  
Minneapolis, MN 55404  
Phone: (612) 339-9121  
Fax: (612) 339-9188  
Email: gzimmerman@meshbesh.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.  
Ben W. Gordon (FL # 882836)  
J. Michael Papantonio (FL # 335924)  
316 S. Baylen Street, Suite 600  
Pensacola, FL 32502-5996  
Phone: (850) 435-7090  
Fax: (850) 436-6090  
Email: bgordon@levinlaw.com

*Attorneys for Plaintiffs*